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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,888	04/14/2004	Julia T. Lathrop	2308/680	7107

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,888	LATHROP ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed December 14, 2007 is acknowledged and has been entered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6, 8, 9, and 11-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Hammond et al (US 2004/0229280).

Hammond et al disclose a method for identifying a ligand having specificity for a protein isoform (page 13 – page 15). Hammond et al disclose contacting one or more ligands such as trimers (para. 0137 & para. 0153) with a sample that contains different protein isoforms such as PrPc and PrPsc. Hammond et al disclose contacting the complexes formed with antibodies (first detection marker) and detecting a signal (para. 0141 & para. 0153). Hammond et al disclose that the ligands can be on beads and complexes formed on these beads. Hammond et al also disclose that the beads with the complexes can be immobilized in an agarose gel (first support). Hammond et al disclose that the protein isoforms can be transferred from the first support to a capture membrane (second support)(Fig. 5 & para. 0153). Hammond et al disclose contacting

the transferred isoforms with antibodies (second detection marker) and detecting a signal. Hammond et al disclose alignment of the spots from the signals and determining the ligands have specificity for the protein isoforms (para. 0145, 0153). Hammond et al disclose that the protein isoform can be modified by digestion or modified by denaturation. Hammond et al disclose that the ligand can be SEQ ID NO 114 (which has a 100% match with SEQ ID NO: 3 of the current application).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al (US 2004/0229280) in view of Drobnik et al (US 4,245,064) or Hammond et al (US 7,217,507).

See above for the teachings of Hammond et al (US 2004/0229280)

Hammond et al (US 2004/0229280) differs from the instant invention in failing to teach the ligand is immobilized directly on the first support.

Drobnik et al teaches that it is known in the art to immobilized ligands to a carrier support and that bonding of the ligand to the support may occur immediately (directly) to the carrier or by means of a linker (indirectly) (col 1, lines 7-42).

Hammond et al (US 7,217,507) teaches that it is known in the art to directly or indirectly attach ligands to a support (col 6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate direct attachment of the ligand to the support as taught by Drobnik et al or Hammond et al (7,217,507) into the method of Hammond et al (2004/0229280) because both Drobnik et al and Hammond et al teach the equivalence of direct and indirect attachment of ligands to a support and the selection of any of these known equivalents to attach the ligand of Hammond et al (2004/0229280) reference would be within the level of ordinary skill in the art.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al (US 2004/0229280) in view of Charlton et al (US 5,989,921).

See above for the teachings of Hammond et al (US 2004/0229280).

Hammond et al differs from the instant invention in failing to teach the ligands are immobilized on the first support prior to contacting with the one or more ligands.

Charlton et al disclose beads having immobilized binding partners used in binding assays. Charlton et al disclose that these beads are entrapped or linked to sorbent material (support) prior to contact with a sample (col 3, lines 39-45 and col 6, lines 16-30). Charlton et al disclose that this provides for improved sensitivity in assays (col 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to immobilize the beads of Hammond et al to the support prior to sample contact such as taught by Charlton et al because Charlton et al teaches that this provides for binding assays with improved sensitivity.

8. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammond et al (US 2004/0229280) in view of Wang (US 2002/0155493).

See above for the teachings of Hammond et al (US 2004/0229280).

Hammond et al (US 2004/0229280) differs from the instant invention in failing to teach the ligands form an array on the first support.

Wang teaches ligands which are immobilized in pre-defined positions on a support to form an array (paragraphs 0003 and 0004). Wang teaches that this provides for the later identification of the ligand. Wang also teaches that this provides for

biological research, clinical diagnostics and drug development and the study of protein-protein interactions (paragraphs 0003 and 0004).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate arrays as taught by Wang into the method of Hammond et al because Wang teaches that this provides for the later identification of the ligand and also teaches that this provides for biological research, clinical diagnostics and drug development and the study of protein-protein interactions.

Response to Arguments

9. Applicant's arguments filed December 14, 2007 have been fully considered but they are not persuasive.

Applicant argues that Hammond et al (US 2004/0229280) is not available as prior art under 35 U.S.C 102(e) because the Declaration of Julia T. Lathrop under 37 CFR 1.132 declares that Ruben Carbonell, the only inventor on Hammond who is not listed as an inventor on the present application did not contribute to the invention of the presently claimed subject matter. This is not found persuasive because even though Ruben Carbonell would be removed, the current application lists Liliana Gheorghiu and Oksana Yakovieva as inventors and the Hammond et al publication does not list Liliann Gheorghiu and Oksana Yakovieva as inventors. Thus, the inventors of the current application do not match up with the inventors of the Hammond et al publication. Therefore, the Hammond et al publication would still be by another and is available as prior art.

Conclusion

10. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gary Counts
Examiner
Art Unit 1641
January 16, 2008

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